UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/455,683	05/31/1995	GRAEME I. BELL	ARCD:177/WIM	8952

7590 01/05/2006

DAVID L. PARKER
FULBRIGHT & JAWORSKI
600 CONGRESS AVENUE SUITE 2400
AUSTIN, TX 78701

EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 08/455,683
Filing Date: May 31, 1995
Appellant(s): BELL ET AL.

Gina Shishima
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/3/05.

(1) ***Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

(2) ***Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 97-102, 109, 112-114, 123 and 137-156 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Cunningham BC and Wells JA "High-resolution epitope mapping of hGH-receptor interactions by alanine-scanning mutagenesis" Science, vol 244, (1989), pp. 1081-1085.

George DC et al. "Current methods in sequence comparison and analysis" In Macromolecular Sequencing and Synthesis – selected methods and applications. Ed. By Schlesinger DH, Alan R Liss, Inc, NY (1988), pp. 127-149

Rudinger J "Characteristics of the amino acids and components of a peptide sequence" In Peptide Hormones. Ed. by Parsons JA. University Park Press, Baltimore. (1976) pp. 1-7.

(10a) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 97-102, 109, 112-114, 123 and 137-156 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims discuss a method of screening a substance for its ability to specifically bind to an opioid receptor using at least 30 nucleotides of SEQ ID NO:11. However, SEQ ID NO:11 is only a partial genomic sequence of a human opioid receptor. The claims are worded in such a way that they encompass screening methods using the full-length kappa opioid receptor encoded by SEQ ID NO:11, which Appellants have not described. As can be seen from claim 97, part (a), the claimed method involves expressing a recombinant opioid polypeptide encoded by at least 30 contiguous bases of SEQ ID NO:11. However, these 30 bases would not encode a full-length opioid receptor, nor necessarily encode the second extracellular loop of the human kappa opioid receptor, which is thought to be essential for ligand binding. SEQ ID NO:11 encodes SEQ ID NO:12, which is a partial amino acid sequence of a human kappa receptor. Appellants argue that the human kappa opioid receptor polypeptide sequence disclosed in the specification has significant homology with the mouse amino acid sequence spanning from amino acids 87-380. These sequences, however, are not identical. The possible effect of changing even one amino acid in a polypeptide can be seen in Cunningham and Wells (1989; Abstract) in which certain single substitutions of alanine in various positions of human growth hormone dramatically altered its binding affinity for the human growth hormone receptor. In addition, George et al. (1988; p. 145) states that: "Sequence-comparison methods will not be able to assess biological relatedness until the structure/function problem is more clearly understood." Additionally, Rudinger (1976; especially the Conclusion) states that "the significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study."

Furthermore, the issue of Applicants not being in possession of the full-length protein encoded by SEQ ID NO:11 is further seen in the Office Action mailed 1/30/01. That Action states that, while the specification does give adequate support for less than full-length opioid receptors, such as the claimed chimeras, it provides no written description for the full-length receptor encoded for by SEQ ID NO:11, since SEQ ID NO:11 does not encode the full-length open reading frame of a human kappa opioid receptor. Therefore, the claims which read, for example, "at least 30 nucleotides of SEQ ID NO:11" would read on the nucleic acid molecule encoding the full-length opioid receptor which Applicants were not in possession of at the time of the filing of this application. However, if Applicants amended the claims to recite the limitation that the nucleotide molecule be no larger than SEQ ID NO:11, so as to not read on the full-length receptor encoded for by SEQ ID NO:11, this rejection will be withdrawn.

(10b) Response to Argument

On page 7 of the Appeal Brief dated 3/3/05, Appellants argue that "an accepted standard for the written description requirement is: 'although the applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed'" and that "written description is met if the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Appellants emphasize that for purposes of the written description inquiry, the invention is whatever is actually claimed. Appellants argue that the claims recite SEQ ID NO:11, in which Appellants were in possession of at the time of the present invention. Appellants argue that the Examiner has not met his burden and that he has only asserted that a representative number of species have not been described and the only issue is regarding the term "comprising." Appellants argue that the claims do not simply recite a function, but a specific structure (SEQ ID NO:11, or part thereof).

On page 10 of the Brief, Appellants argue that they have provided a representative number of species and that there is no evidence that there is unpredictability with respect to the remaining species. Appellants further argue that "the claimed invention covers processes involving an opioid receptor polypeptide having or encoded by a particular sequence (either SEQ ID NO:12 and/or SEQ ID NO:11). Thus Appellants have described a representative number of species that are representative of the entire genus because the variations of any opioid receptor polypeptide are limited by the recited structural limitations." Appellants further argue that there is no evidence that there is no unpredictability with respect to the remaining species.

On page 11 of the Brief, Appellants argue that the Examiner states that "even in the absence of a full-length receptor, the artisan would know how to make and use the present invention." Appellants further argue that substantial information exists with regard to opioid receptor screening methods.

In response, the Examiner states that all of the claims have been rejected under written description even though they are of different scope since all claims depend from claims which recite "comprising SEQ ID NO:11." Therefore, all of these claims read on the full-length opioid receptor encompassed by SEQ ID NO:12 (the polypeptide encoded by SEQ ID NO:11).

In response to Appellants' argument that "...the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed'" and that "written description is met if the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter," the Examiner provides the

following remarks. It is, actually, clear from Appellants' arguments that they have not, in fact, invented what is claimed. As seen in claim 97, the independent claim, Appellants have used terms such as "specifically bind to an opioid receptor" by "expressing a recombinant opioid receptor polypeptide." This implies that Appellants were actually in possession of an opioid receptor polypeptide. This is not the case as Appellants were only in possession of a partial sequence which would not be considered an opioid receptor polypeptide by one of ordinary skill in the art. When considering the phrase "opioid receptor polypeptide" the artisan would envision a full-length receptor, not a partial sequence. Therefore, it is not understood how Appellants were able to express a recombinant opioid receptor polypeptide when they were not in possession of such a molecule. If Appellants were to actually claim what they have described, they would have recited something along the lines of "expressing a recombinant opioid receptor fragment." This, however, would not have remedied the issue, since the claim still recites "**at least 30 contiguous bases**" (emphasis added), which would still read on the full-length receptor. Therefore, contrary to Appellants' arguments, the Examiner has met his burden by asserting that a representative number of species has not been described. In fact, no species has been described. Again, the claims recite "recombinant opioid receptor polypeptide" which reads on the full-length receptor. No full-length species has been described in the specification. While the claims may recite a specific structure, they do not recite a specific structure of a full-length kappa opioid receptor.

Finally, contrary to Appellants argument that "there is no evidence that there is no unpredictability with respect to the remaining species," the Examiner disagrees. One of ordinary skill in the art would have serious reason, respectfully, to question any assertion that another artisan could be able to predict the exact structure of a protein given only a portion of its sequence, regardless of homology to other known species. The only way an exact amino acid/nucleotide sequence could be known is by sequencing the actual molecule(s).

It is believed that all pertinent arguments have been addressed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this Examiner's Answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Robert Landsman
Primary Examiner
Art Unit 1647

Robert Landsman
January 3, 2006

Conferees
Brenda Brumback

DAVID L. PARKER
FULBRIGHT & JAWORSKI
600 CONGRESS AVENUE SUITE 2400
AUSTIN, TX 78701

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600